Date: 9/5/2018
GAIN Report Number: MO1846

Morocco

Post: Rabat

Code of Procedures for Animal Feeds and Additives

Report Categories:
SP2 - Prevent or Resolve Barriers to Trade that Hinder U.S. Food and Agricultural Exports
FAIRS Subject Report
Grain and Feed
Sanitary/Phytosanitary/Food Safety
Biotechnology - GE Plants and Animals
Oilseeds and Products

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Report Highlights:
This report contains the unofficial translation of Code CP 03/DSV/14 regarding additives, premixes, and supplements for animal feed. This code has an impact on $300 million of U.S. agricultural products.

ONSSA	PROCEDURE CODE N. 3 National Food Safety Office for Food Products	Date: August 18, 2014 Code: CP 03/DSV/14 Version: A

CODE OF PROCEDURE RELATING TO THE AUTHORIZATION

OF

ADDITIVES, PREMIXES OF ADDITIVES AND SUPPLEMENTARY FEEDINGSTUFFS FOR ANIMAL FEEDING

Abbreviations

ONSSA: National Food Safety Office for Food Products

AMM: Marketing Authorization

DPIV: Division of Pharmacy and Veterinary Inputs

Distribution: External, DSV, DR ONSSA, SV		
Editorial: Division of Pharmacy and Veterinary Inputs		
Examination: Dr. A. EL ABRAK **Function: Director of Veterinary Services** **Date: August 18, 2014**	**Revision: Dr. S. BAKKALI** **Function: Quality Assurance Manager** **Date: August 18, 2014**	**Approval: Mr. A. BENTOUHAMI** **Function: Director General of ONSSA** **Date: August 18, 2014**

SUMMARY PAGE

I- Preamble:

-Considering the law n ° 25-08 establishing ONSSA and the attributions and missions of the Office National Sanitary Security of Food Products relating to the application of government policy in the area of plant, animal, and food safety from the raw materials to the final consumer, including foodstuffs for animal nutrition.

- Whereas the residues of certain food additives may have harmful consequences to the health of the consumer.
- Considering the need for transparent and harmonized procedures for the authorization of additives, which make it possible to control the use of these products, without being an economic burden;

- Considering the Dahir promulgating Law No. 28-07 on the safety of food products and its implementing decree;

- Considering the publication on the official bulletin of the Minister of Agriculture and Fisheries No 1490-13 of 03/05/2013 fixing the list and the maximum levels of undesirable substances in feed and the list and limits of use of additives, premixes, compound, and complementary feeds for animal feed;

- Considering the remarks and recommendations of the economic operators concerning the Circular N ° 526 / DE / DSA / LNCMV of 09/03/2009.

The authorization procedure for additives, premix additives, and complementary foods is defined in this code of procedures.

II - Scope of application:

This code applies to additives, additive premixes, and foods whether imported or manufactured in Morocco.

III - Definitions:

1 / Additive: An additive is any substance or preparation used in animal feed in order to:

-influence the characteristics of raw materials for animal feed or compound feedingstuffs or animal products, or,

-to satisfy the nutritional needs of animals or to improve animal production, particularly in influencing the gastro-intestinal flora or the digestibility of food products given to animals; or

-to bring into the diet favorable elements to achieve nutritional objectives individuals, or to meet the specific nutritional needs of animals; or

-to prevent or reduce nuisances caused by animal waste or to improve the animal environment;

2 / premix of additives: additives mixed with one another or mixtures of one or more additives with substances constituting supports which are intended for the manufacture of animal feed. For the purpose of this definition, "premixes" are premixes.

3 / Nutritional Supplements: May be considered premixes for special purposes.
They are defined as single substances or substances intended solely for nutritional purposes and intended for temporarily supplementing animal feed to meet their temporary increased needs in certain circumstances of the breeding or their life.

Thus, as their name indicates, nutritional supplements are intended, not to substitute for the usual foods, but to supplement the ration for a particular nutritional purpose. They are characterized by low incorporation rates, lower than the daily quantities allowed. They consist mainly of authorized additives and raw materials. Nutritional supplement products are exclusively nutritional. The growth factor additives are excluded. They can be administered, directly, by drinking water or in the food.

4 / Complementary feeds for animals: feed mixtures which, because of their composition, provide the daily ration only if they are combined with other feeds. In this category, belongs nutritional supplements.

IV - Authorization procedure

The authorization of a food additive, a complementary food or a premix of animal nutrition additives by the competent administration is conditioned by the study of a technical file relating to this product. This file is constituted and deposited by the applicant economic operator of this authorization.

1- Identification of the applicant:
The applicant for an authorization for an additive, a complementary food or a premix of animal feed additives must submit an information sheet in the form set out in Annex 2.

2- Composition of the authorization files:
2-1- For the additives listed in the order establishing the list and the maximum levels of the feed substances and the list and limits of use of the additives, premixes, compound feeds, and complementary animal feed:
The additives listed in the order establishing the list and the maximum levels of undesirable substances in feed and the list and limits of use of additives, premixes, compound feedingstuffs, and complementary feedingstuffs for animal feed are allowed to import and do not require additional authorization.

2.2. For additives not included in the order establishing the list and the maximum levels of undesirable substances in animal feed and the list and limits of use additives, premixes, compound feeds, and complementary foods intended for animal feed
Authorization of new food additives for addition in animal feed is carried out after favorable opinion of the competent ONSSA’s services, after a technical study comprising of an administrative part and a technical part.

2.2.1. Administrative part comprising:

- The letter of request for authorization (see model in appendix 1);
- The product data sheet mentioning (see model in appendix 3);
- The official positive list showing that the additive in question is officially registered on the said list (for imported products);
- Or failing that, the certificate of the official authorities of the country of origin of the addendum of non-requirement of the authorization to put on the market within the meaning of the legislation on veterinary medicinal products;
- The certificate of sale in the country of origin of the additive (for imported products);
- The certificate attesting that the cumulative radioactivity thresholds do not exceed international standards admitted;
- The certificate attesting the absence of hormones;
- The certificate attesting that the dioxin level does not exceed accepted international standards;
- The certificate attesting the absence of products of animal origin except gelatin of non-ruminants for coating additives;
- For additives derived from biotechnology techniques based on genetically modified organisms (GMO), an official commitment of the manufacturer confirming the total destruction of GMOs at the end of the manufacturing process.

2.2.2. Technical part comprising:

a- The analytical file of additive:

- The identity of the additive and its monograph (name, type of additive, physical state, composition qualitative and quantitative ...);
- The physicochemical and technological properties of the additive (stability, physicochemical interactions ...);
- The conditions of use of the additive (expected uses in animal feed, minimum contents and maximum incorporation, adverse effects, other jobs ...);
- The manufacturing process (manufacturing methodology);
- control methods for establishing qualitative and quantitative composition; stability during the food preparation and content in premixes and foods;
- The control methods of the additive in the food;
- Residue control methods in animal and animal products;
- The additive analysis bulletin duly dated and signed by the technical manager of the laboratory having performed the analysis;
- A sample in sufficient quantity for conformity analysis;
- A labeling specimen in accordance with the provisions of Chapter V of this Code of Procedure.

b- The study file of the effectiveness of the additive:

Studies to highlight the expected effects of the food additive.

c- The study dossier of the safety of the additive relating to:

* The study of the safety of the additive on the target species (toxicological effects, tolerance study, determination of the factor of safety ...);
* The study of the residues of the additive in animal and animal products (studies in the practical conditions of use to determine the withdrawal period before slaughter and the guarantee of consumer safety);
* The study of excreted residues and their effects on the environment.

NB: For records of vitamins, trace elements, mineral salts and amino acids, efficacy, and safety studies are not required.

2.3. For a premix or complementary food:
Each of the additives constituting the premix or the complementary food shall be included in the list of annexed to the order laying down the list and the maximum levels of undesirable substances as well as the list and limits of use of additives, premixes, compound feed and complementary feeds for animal feed. If one of the ingredients is not on the list, a file relating to this ingredient must be filed in accordance with point 2.2 of this code of procedures.

For premix additives and complementary foods, the composition of which includes substances listed in the list of additives annexed to Order No 1490-13, it is necessary to provide to the Division of Pharmacy and Veterinary Inputs (DPIV), for the first time import (and at least 15 days before this importation), the following documents:

- The letter of request (annex 1),
- The applicant specification sheet (Annex 2),
- The product data sheet (annex 3),
- The qualitative and quantitative composition of the product,
- The minimum and maximum levels of incorporation of the product,
- The product label,
- The certificate indicating that the premix (or complementary food) is composed in full with substances on the list of additives (Annex 4).

This measure does not apply to premixes containing anticoccidials or enzymes. The applicants for these products will have to submit a complete registration dossier to obtain an import authorization.

3. Modalities and authorization steps
3.1. Filing of the application
Applications for authorizations of additives, premixes or feeds for incorporation into animal feed shall be in the name of the Director General of the National Office for Sanitary Safety of Food Products, and deposited with the Division of Pharmacy and Veterinary Inputs, accompanied by an acknowledgment of receipt. They receive a number that allows the applicant to follow up without difficulty. Imports can only take place after the issuance of ONSSA's favorable opinion.

3.2. Technical evaluation of the file
Applications for authorization of feed additives must be deposited 20 days before the date of commission. The Pharmacy and Veterinary Inputs Division, which prepares an evaluation report based on the elements provided, will study these files.

Each supplement filed and each correspondence sent to the DPIV must mention the number of the file and the name and contact information of the person responsible for following up the file.

3.3. Technical Committee on Food Additives for Animal Feed
It is instituted within the Division of Pharmacy and Veterinary Inputs a commission on technical food additives for animal feed composed of:

- Chief of the Animal Health Division or his representative, member;
- Head of the Veterinary Division of Food Hygiene or his representative, member;
- Chief of the DPIV or his representative, spokesman.

This commission, which meets **once every three months** and whenever necessary, on the requests made by the operators on the basis of an evaluation report drawn up by the DPIV.

The final opinion of the commission will be notified to the applicant by ONSSA. Any request for information will be notified by letter from the DPIV.

Each meeting of the commission will result in a report that will be circulated to members by the Division of Pharmacy and Veterinary Inputs.

An importation authorization is prepared by DPIV and signed by ONSSA's Director General Files, which have received a favorable opinion by the additives technical commission.

3.4. Positive national lists of additives, premixes, and complementary feeds:
DPIV is responsible for regularly updating the list and the limits for additives use, premixes, compound feeds, and complementary feeds, by transmitting them at the end of each year to the Regulatory and Standardization Division (ONSSA) for the update of the order establishing the list and the maximum levels of undesirable substances in animal feed as well as the list and limits of use of additives, premixes, compound feed and complementary foods intended for animal feed.

For additives, the lists cited below are published on the ONSSA website:
- The list affixed to the order stating the maximum levels of undesirable substances in animal feed and the list and limits of additives, pre-mixtures, compound feedingstuffs, and complementary foods intended for animal feed ;
-The list of premixes of authorized additives;
-The list of authorized complementary foods;
Products already registered on these lists do not require additional authorization for their imports.

V - Special provisions
1. Labeling
Packaging and containers containing additives, premixes and complementary foods must bear the following indications, written in Arabic or French, and in clearly marked characters legible and indelible:

- The name or the commercial name of the product;
- The dates of manufacture and expiry;
- Lot number;
- Net weight or net volume;
- Concentration of the active ingredient (s);
- The words 'exclusively for the manufacture of animal feed' for additives and premixtures, and 'exclusively for animal feed' for complementary foods;
- The name or business name and the address or registered office of the manufacturer of the product;
- The incorporation content in the final feed intended for animal feed;
- Target species and age of animals;

- The withdrawal period of the product before slaughter;
- If applicable, the name or business name and address of the person responsible in Morocco for the indications on the labeling (producer, packer, importer, reseller or distributor);

In all cases, these indications must be in accordance with the conditions laid down in the technical sheet of the feed additive intended for animal feed.

2. Traceability:
The applicant for the authorization, whether manufacturer, importer or distributor, must put in place the provisions for traceability of additives, premixes or feedstuffs products it manufactures, imports or markets and retains all registrations to ensure their traceability.

The following information must be recorded, (for example as a register, computer file, receipt, and/or delivery note), updated and archived for a period of minimum of one year after the delivery of the manufactured or marketed products:

a) For the products received
- The trade name or the specific name of the product;
- The nature and quantity of each product received;
- The dates of manufacture and reception;
- The name of the manufacturer or shipper;
- The lot number of each product received.

(b) For delivered products
- The name and surname of each client;
- The address and identification of establishments or intermediaries to which each additive, premix, or nutritional supplement is delivered;
- The trade name and quantities of the delivered products;
- Batch numbers and dates of manufacture;
- The delivery date.

3. Recall procedure
In order to ensure the health security of the national herd and the safety of the consumer, the importer or distributor must set up the recall procedure for its products and utilize it whenever necessary.

4. Deadlines for validity of applications
For reasons of strict management of authorization applications, the files for which there have been two requests for supplements and those that have not been completed for more than three months will be considered inadmissible. The applicant must, if he wishes to obtain the import authorization, provide a new request.

5. Registration of products by exporters
No product can be authorized if an applicant established in Morocco does not request it from ONSSA. However, to optimize product registrations and ensure the protection of the industrial property, foreign companies (especially those who own products), may engage directly with the competent Moroccan

authorities in registration of their products on applications accompanied by complete files in accordance with provisions of this Code of Procedure.

Applications are made on behalf of ONSSA's General Director and filed with the DPIV who assesses them. Requests for complements and/or favorable registration notice formulated by the Technical Committee on Additives will be sent to the applicant.

For complete records that have received a favorable registration notice, the national companies wishing to import them, must file an application for an import authorization with the DPIV. The import authorizations will be established after verification that they are customers approved by the provider and authorized to exploit the data of the files filed by the foreign owner folder.

6. Inspection

In accordance with the provisions of this Code of Procedure, inspections may be carried out with companies importing, manufacturing or marketing additives, premixes, and complementary feeds.

ANNEX 1: MODEL LETTER OF APPLICATION FOR AUTHORIZATION:
Company letterhead

Date: ……..

To
Mr. Director General of ONSSA

Subject: Application for import authorization * / manufacturing * of the additive.....

Mr. Director,

I, the undersigned, Mr ..... (Surname and first name); of the company..... (Company name and address) ... ., asks the competent authorities to kindly grant us import * / manufacturing * / marketing * authorization for the additive *, premix additives * or the complementary food * referred to as .....

The product ... (trade name or brand name) ....., is a ... (type of product) ..... composed of (qualitative composition) .....

It is manufactured by ... .. (Name and address of the manufacturer) .....
And distributed by .... (Name and address of the dealer or distributor) ....

In its country of origin, this product is registered and / or licensed as .....
According to the regulations ....
The product ..... is intended for animal species.....
The recommended incorporation rate in the feed of these animals is ....

In case of request for additional information by the technical commission, please kindly contact Mr. ...., Tel: ....., e-mail address .....

Please accept, Mr Director General, the expression of my best regards.

Signed: .....

(*): circle applicable selection.

ANNEX 2: TECHNICAL SHEET APPLICANT FOR AUTHORIZATION OF AN ADDITIVE, PREMIX OR COMPLEMENTARY FOOD OF ANIMAL FEED

Corporate name:

Planned trade name for placing on the market:
Name and address of the company providing the manufacturing, conditioning and control:

Name of the responsible:

Applicant's address:

Contact information:
1- Telephone
2- Fax
Activities:

Type of customers (breeders, feed producers ...):

Location of activities:

Local Description:

Technical note:

1- Locals
(Production, packaging and storage, capacity ...)
2- Staff
(Number, qualification ...)
3- Hardware
(Nature, quantity, capacity ...)
4- Activities
(Nature, synthetic summary of production, control ...)

APPENDIX 3: TECHNICAL SHEET OF AN ADDITIVE, A PREMIX OF AN ANIMAL FEED FOOD SUPPLEMENT

Commercial name intended for placing on the market

Name and address of the applicant

Name and address of the company providing the manufacturing, conditioning and control

Type of additive, premix or nutritional supplement depending on the main effect (Antibiotic, coccidiostatic, conservative agent, etc ...)

Destination of additive, premix, or supplement nutritional (sales, direct use by importer, other…)

Qualitative and quantitative composition

- Active substances
- Other components
- Impurities

Destination species

Form and presentation

Other known uses of the active substance or preparation

Biological properties of the additive, premix or nutritional supplement

Duration of product stability and storage conditions

Stability time in pre-mixes

Stability time in foods

Predicted concentrations in premixes and foods:

- Contents of active substance.
- Weight percentage content for premixes
- Content in mg/kg for food.

Waiting time

Physicochemical interactions /

- Incompatibilities with food
- Incompatibility with other additives
- Incompatibilities with drugs

Adverse effects

Precautions of use

Annex 4

Certificate certifying that premix / complementary food is composed in full with substances on the list of additives annexed to the decree No. 1490-1413

Designation of the company: .....

Product designation:……..……..
Name of manufacturer: .....
Native country:……..
Type of product: ……..…..
Composition of the product as additive (s): .....
.....
.....
.....
.....
.....
.....

I, the undersigned Mr / Mrs ....., As ...., certify that the product quoted above is composed entirely with additives listed on the decree of the Minister of Agriculture and Maritime Fisheries No 1490-13 of 03/05/2013 fixing the list and maximum levels of undesirable substances in feed as well as the list and limits of use of additives, premixes, compound feeds and complementary feeds for animal feed.

Date: ..... Signature:

Document History Sheet

Date	Version	Nature
18/08/2014	A	Creation